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| EXAMINER | |
|---|---|
| MACAULEY, SHERIDAN R | |
| ART UNIT | PAPER NUMBER |
| 1651 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/554,290 | REDMOND ET AL. | |
| | Examiner | Art Unit | |
| | Sheridan R. MacAuley | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *4-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 8-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/2006, 10/25/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-27 are pending.

### *Election/Restrictions*

1. Applicant's election without traverse of the species of the subject matter of claim 3, in the reply filed on September 19, 2007, is acknowledged.

2. Claims 4-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim.

3. Claims 1-3 and 8-27, insofar as they read upon the elected species, are examined on the merits in this office action.

### *Specification*

4. The use of trademarks such as TRAMFLOC, SURFLOC, AQAUMARK, SUPERFLOC, TERMAMYL, SPEZYME, CELITE and PHAOCOCELL (for example, on pages 15-19) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

5. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### *Claim Objections*

6. Claim 10 is objected to because of the following informalities. It is recommended that the claim be amended as follows: The term "than10%" should be changed to "than 10%". Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3 and 8-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The term "an effective amount" in claim 1 is a relative term which renders the claim indefinite. The term "an effective amount" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is further unclear what effect applicant expects for the "effective amount" to achieve. For instance, and effective amount could be 1 mg/g, 10 mg/g or 100 mg/g.

### *Claim Rejections - 35 USC § 102*

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3 and 8-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Westerlund et al. (Carbohydrate Polymers, 1993, 20:115-123). The claims are directed to a pharmaceutical composition comprising an effective amount of beta (1-3) beta (1-4) glucan (referred to as beta-glucan in this office action), specifically wherein the beta-glucan has a purity of at least about 75% and contains less than 10% ash impurities, less than 10% protein impurities, specifically a purity of 92% and contains less than 3.5% ash impurities, less than 3.5% protein impurities, and less than 1% lipid impurities, and a purity of 5 to 100 NTU, and less than 3.5% protein impurities, and an effective amount of a botanical abstract, specifically an extract of oat grain. The claims further recite that the beta-glucan is produced according to a method comprising: (i) extracting the milled cereal grain or the milled part of the cereal grain with an alkaline solution to produce an extract containing at least about 0.4 weight % beta glucan; (ii) removing insoluble material, and removing particulate material having a particle size of greater than about 0.2 micron from said extract to produce a purified extract; (iii) adding from about 10% to about 25% weight/weight (w/w) of a $C_1$-$C_4$ alcohol to the purified extract to precipitate the beta glucan; and (iv) isolating the beta glucan. Claims 14 and 15 recite that the alcohol of step (iii) of claim 13 is about 10% to about 20% (w/w) of an alcohol, specifically ethanol. Claim 16 further limits claim 13 by reciting the limitation that the step of removing the particulate material comprises adding a flocculant, a coagulant of both a flocculant and a coagulant to the extract to coagulate particulate material having

a particle size of greater than 0.2 microns, and removing coagulated material from said extract; digesting starch material in said extract; and filtering out particulate material having a particle size of greater than 0.2 microns from said extract to produce a purified extract. Claim 17 further limits claim 16 by reciting the limitation that the starch material is digested with an enzyme. Claim 18 further limits claim 17 by reciting the limitation that, prior to digestion of starch material, the alkaline solution is neutralized. Claims 19 and 20 recite the method of claim 18 wherein, following the digestion of the starch material, the enzyme is inactivated, specifically by acidifying the neutralized solution. Claims 21 and 22 further limit claim 17 by reciting the limitation that the enzyme is an amylase, specifically one which requires a calcium cofactor. Claim 23 further limits claim 1 by reciting that the cereal is selected from the group recited in the claim. Claim 24 further limits claim 13 by reciting the limitation that the pH of the alkaline solution is from about 9 to about 10. Claim 26 further limits claim 13 by reciting the limitation that step (iii) conducted at a temperature of from about 1 degree C to about 10 degrees C. Claim 27 further limits claim 13 by reciting the limitation that the method further comprises one or more step of dissolving the isolated beta glucan in an aqueous solution, precipitating the beta glucan by adding about 10% to about 25% (w/w) of the $C_1$-$C_4$ alcohol to the aqueous solution, and isolating the beta glucan.

12. Westerlund teaches a composition comprising beta-glucan extracted from oat bran (abstract). The glucan of Westerlund has a purity of up to 99% (abstract). Because the beta glucan of Westerlund is not 100% pure, the composition would comprise another extract from oat, i.e. a botanical extract. Although Westerlund does

not disclose the specific percentages of ash, protein and lipid impurities, it can be inferred that a composition which is 99% pure would not contain more than 1% of any impurity, and would have the claimed clarity value. Futher, although the methods for the production of the composition of Westerlund are not identical to the methods by which the claimed composition is made, the composition of Westerland does not appear to be different from the claimed composition. Therefore, the composition of Westerlund would have the same inherent properties of the claimed composition.

13. Thus, Westerlund anticipates all of the limitations of the claims.

14. Claims 1-3, 8-10 and 12-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhatty (5,518,710). The claims are directed to a pharmaceutical composition comprising an effective amount of beta (1-3) beta (1-4) glucan (referred to as beta-glucan in this office action), specifically wherein the beta-glucan has a purity of at least about 75% and contains less than 10% ash impurities, less than 10% protein impurities, and a purity of 5 to 100 NTU, and less than 3.5% protein impurities, and an effective amount of a botanical abstract, specifically an extract of oat grain. The claims further recite that the beta-glucan is produced according to a method comprising: (i) extracting the milled cereal grain or the milled part of the cereal grain with an alkaline solution to produce an extract containing at least about 0.4 weight % beta glucan; (ii) removing insoluble material, and removing particulate material having a particle size of greater than about 0.2 micron from said extract to produce a purified extract; (iii) adding from about 10% to about 25% weight/weight (w/w) of a $C_1$-$C_4$ alcohol to the purified

extract to precipitate the beta glucan; and (iv) isolating the beta glucan. Claims 14 and 15 recite that the alcohol of step (iii) of claim 13 is about 10% to about 20% (w/w) of an alcohol, specifically ethanol. Claim 16 further limits claim 13 by reciting the limitation that the step of removing the particulate material comprises adding a flocculant, a coagulant of both a flocculant and a coagulant to the extract to coagulate particulate material having a particle size of greater than 0.2 microns, and removing coagulated material from said extract; digesting starch material in said extract; and filtering out particulate material having a particle size of greater than 0.2 microns from said extract to produce a purified extract. Claim 17 further limits claim 16 by reciting the limitation that the starch material is digested with an enzyme. Claim 18 further limits claim 17 by reciting the limitation that, prior to digestion of starch material, the alkaline solution is neutralized. Claims 19 and 20 recite the method of claim 18 wherein, following the digestion of the starch material, the enzyme is inactivated, specifically by acidifying the neutralized solution. Claims 21 and 22 further limit claim 17 by reciting the limitation that the enzyme is an amylase, specifically one which requires a calcium cofactor. Claim 23 further limits claim 1 by reciting that the cereal is selected from the group recited in the claim. Claim 24 further limits claim 13 by reciting the limitation that the pH of the alkaline solution is from about 9 to about 10. Claim 25 recites that step (i) of the method of claim 13 is carried out for a period of 15 to 45 minutes. Claim 26 further limits claim 13 by reciting the limitation that step (iii) conducted at a temperature of from about 1 degree C to about 10 degrees C. Claim 27 further limits claim 13 by reciting the limitation that the method further comprises one or more step of dissolving the isolated

beta glucan in an aqueous solution, precipitating the beta glucan by adding about 10% to about 25% (w/w) of the $C_1$-$C_4$ alcohol to the aqueous solution, and isolating the beta glucan.

15. Bhatty teaches a composition comprising beta-glucan extracted from oat bran (col. 5, line 50-col. 6, line 22). The glucan of Bhatty has a purity of at least about 80% and contains 0.5% nitrogen and about 3.7 percent ash (col. 9, table III). Because the beta glucan of Bhatty is not 100% pure, the composition would comprise another extract from oat, i.e. a botanical extract. Although Bhatty does not disclose the specific percentages of protein and lipid impurities, the method of making the beta-glucan in the composition of Bhatty is nearly identical to the disclosed method of producing the claimed composition. Therefore, the composition of Bhatty would have the same inherent properties of the claimed composition. Specifically, Bhatty teaches that the beta glucan (including beta (1-3) beta (1-4) glucan; col. 2, lines 40-43) is extracted from milled cereal grain (including cultivars of oat; col. 2, lines 37-39; col. 3, lines 12-21) comprising extraction with an alkaline solution with a pH from 8-14 (col. 3, lines 22-26), removing insoluble (particulate) material by centrifugation, dialysis or filtration (note that the particles of Bhatty would inherently be larger than 0.2 microns; col. 3, lines 46-48), adding about 20% to about 90% alcohol (including the $C_1$ to $C_4$ alcohols methanol, ethanol, propanol and butanol; col. 3, line 63-col. 4, line 5), and isolating the beta-glucan (col. 4, lines 5-8). The extract produced by the initial extraction with an alkaline solution of Bhatty would inherently contain from at least about 0.04 to about 1.3% beta glucan, because Bhatty discloses the use of cereals and milled cereal grains as starting

materials which comprise from about 6.6 to 13.4% beta glucan, and that about 63-95% of the beta glucans are extractable, therefore the starting materials contained from about 4.2-12.7% extractable beta glucans (63% of 6.6% is about 4.2%, and 95% of 13.4% is about 12.7%; Tables II and IV); the cereal to solvent ratios used range from 1:10 to 1:100, therefore the alkaline extracts would contain about 0.04-1.3% beta glucans (4.2% divided by 100 is about 0.04%, and 12.7% divided by 10 is about 1.3%; col. 3, lines 38-44); since the extract of Bhatty is produced by the methods claimed in the instant application, the extract produced by Bhatty would have inherently contained beta (1-3) beta (1-4) glucan within the claimed range. Bhatty teaches that the step of removing particulate material can comprise the addition of a flocculant and/or coagulant to coagulate particulate material, which would have a particle size of greater than 0.2 microns (an acid is used as the coagulant/flocculant; col. 3, lines 48-54), removal of particulate material from the extract by centrifugation (col. 3, lines 52-54), digestion of starch material in the extract using an enzyme (col. 3, lines 53-56) and filtering out of particulate material from the extract (col. 3, lines 63-65). Bhatty teaches that the pH of the alkaline solution can be adjusted to about 7 (neutral) prior to enzymatic digestion (col. 3, lines 48-56). Bhatty teaches that step wherein the alcohol is added to the beta glucan extract can be conducted at 4 degrees C (Fig. 1, step 7). Bhatty teaches the further step of dissolving the beta glucan in an aqueous solution and precipitating again with alcohol and isolating the beta glucan by centrifugation (Fig. 1, step 9). Although Bhatty does not teach the inactivation of the amylase, specifically one which does not require a calcium cofactor, using an acid, or the claimed period of extraction by which

the claimed composition is produced, the composition of Bhatty appears to be identical to the claimed composition.

16. Therefore, Bhatty anticipates all of the limitations of the cited claims.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A Davis/
Primary Examiner, AU 1651